

Summary of Teleconference

Date: March 27, 2019, 1:00 PM EST

Initiated by: CBER

CBER Attendees: Doran Fink, MD, PhD
Bharat Khurana, DVM, PhD, MBA

BN Attendees: Renee Boerner, PhD
Barbara Petzold

Subject: To notify Bavarian Nordic (BN) that the monkeypox indication would be subject to PREA requirements

Summary:

CBER stated that as communicated earlier during the mid-cycle meeting, we have received inquiries from external stakeholders in the US government regarding licensure of vaccines for prevention of monkeypox. Subsequent to further internal discussion, CBER determined that the non-human primate (NHP) data already submitted to the original BLA 125678/0 would likely support the indication for prevention of monkeypox infection in adults 18 years of age or older; however, BN would be responsible for meeting the Pediatric Research Equity Act (PREA) requirements for the “prevention of monkeypox” indication. Unlike the situation for the “prevention of smallpox” indication, for which CBER agreed that studies would be impossible or highly impracticable to conduct in pediatric populations, CBER’s preliminary assessment is that it will be difficult to justify a full-waiver for pediatric assessments of the vaccine for prevention of monkeypox. If BN agrees with a “prevention of monkeypox” indication for the original BLA submission, BN will be responsible for submitting an amendment to the current BLA that includes request(s) for waiver(s) and/or deferral(s), and rationales to support those requests, to address PREA. Any deferred studies will be considered as post-marketing requirements.

CBER added that it is now up to BN to decide how to proceed with the “prevention of monkeypox” indication.

BN asked about the time-frame for submitting an amendment with the necessary information. CBER replied that for consideration of including a “prevention of monkeypox” indication with the original BLA, the amendment would need to be submitted within one month following this teleconference. CBER added that if BN wants to include the indication for “prevention of monkeypox infection” after the current licensure, BN may submit an initial Pediatric Study Plan (iPSP) according to the timelines specified in the FDA Draft Guidance on content and process for submitting iPSPs (March 2016).

BN asked if they are required to also include the protocols for the studies they plan to request deferral. CBER responded that they are not required to submit the protocol for their proposed deferred studies at this time. CBER asked BN to include a high-level summary of each proposed deferred study that includes the age-group, reason for deferral request, and planned dates of protocol submission, study initiation, study completion, and final report submission.

CBER added that BN should propose the rationale(s) to support requests for waiver(s) and/or deferral(s) and referred to the draft guidances on iPSPs and on complying with PREA (September 2005) for additional information on options for applicable rationales.

CBER offered BN to contact Dr. Khurana if they still have any questions.

Meeting ended!